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Atty. Docket WEG-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants: Edwin Wegman, et al.  
Serial No.: 08/757,904  
Filed: November 27, 1996 (as a File Wrapper  
Continuation of Serial No. 08/356,112  
filed December 15, 1994).  
For: REDUCTION OF ADIPOSE TISSUE  
Examiner: Ms. Jean C. Witz  
Group Art Unit: 1651

APPELLANTS' REPLY BRIEF

This is in reply to the Examiner's Answer of <sup>August</sup> ~~June~~ 17,  
1998.

I. The Examiner has hit the nail on the head in  
stating:

"It appears that the difference between Appellants'  
position in this dispute and Examiner's position is  
one of claim interpretation." (Page 5, lines 5-6 of  
Examiner's Answer.)

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Appellants' claim reducing the amount of adipose tissue at selected locations in the body <sup>by action</sup> of collagenase on the tissue."

Appellants' interpretation is that "reducing \_\_\_\_" means removing adipose tissue, or causing it to disappear, from selected locations.

The Examiner's interpretation is that when collagenase acts on adipose tissue at a selected location, adipose tissue no longer exists there; hence, the amount of adipose tissue has been reduced (Examiner's Answer, page 7, lines 12-19).

The Examiner asserts that Appellants' analysis of the claim language is too narrow. By the same token, the Examiner's analysis of the claim language is too narrow. It is time to apply common sense to resolve this matter.

Appellants' interpretation ~~was~~ necessarily follows from the specification:

-- "Liposuction...mechanically removes fat from the subcutaneous tissues" (page 1, lines 1-4).

-- "The invention provides a new method to obtain the reduction of...excess amounts of unsesthetic and/or redundant subcutaneous adipose tissue." "In a single treatment, reduction of the tissue from its original

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volume may range from 25% to 75% and higher" (page 2, lines 17-19). "The method is used to rid the patient of unwanted subcutaneous fat cells without necessity of incisions..." (page 2, lines 10-13, 17-19, 23-24).

-- "Usually for cosmetic reasons, it may be desirable to reduce the amount of subcutaneous fat at selected locations" (page 3, lines 18-20).

~~Page 15, entire.~~

#### EXPERIMENT E

No. of rats: One Zucker

Please see  
(copy all of Experiment E, page 15.

The applicants' interpretation of the claims is supported by the specification, particularly the portions above cited, and especially Experiment E that demonstrates an average weight loss of the fat pads of over 25%, cf. claims 19 and 21.

The claim words:

"A method of reducing for cosmetic purposes the amount of adipose tissue at selected locations in the body;" are modified by e.g., the last three lines of claim 1: "and the body metabolizing fat released from said adipose tissue whereby the amount of adipose tissue at said selected locations is reduced for cosmetic purposes."

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Likewise, "for cosmetic purposes" modifies "reducing...the amount of adipose tissue at selected locations." Where fat is metabolized, it disappears. For cosmetic purposes to be accomplished, adipose tissue must be removed.

II. The Examiner, in interpreting "reducing the amount," not only relies on a narrow meaning that is at odds with the meaning dictated by the specification, but also ignores and/or minimizes the portion of the claims discussed in the preceding paragraph. The Examiner actually denies that Appellants' experimental data shows "that the bodies of the rats treated with the collagenase metabolized any of fat released" (original emphasis) (Examiner's Answer, page 9, lines 1-3); "Appellants' assertions that the fat has been metabolized is simply not supported by any evidence of record" (Examiner's Answer, page 9, last two lines).

This denial of the operability, and thus usefulness, of the invention is a "submarine" rejection under 35 U.S.C. 101. It does not meet the current U.S. Patent Office guidelines on utility. As will now be shown, the faulty reasoning on page 9 of the Examiner's Answer does not rebut Appellants' credible assertion that fat is

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metabolized and the logical conclusion drawn from the experimental data. Following are quotations from specified lines of page 9, and Appellants' reply thereto.

First, it has never been shown in the experimental data as to how much fat (not tissue) is released as a result of the claimed method or that the bodies of the rats treated with the collagenase metabolized any of fat released" [original emphasis] (page 9, lines 1-3).

In defining adipose tissue at page 6, lines 8-13, the Examiner states, inter alia, "The storage cells are called adipocytes and are the main component of the tissue mass.... Very little matrix is present in adipose tissue...." Appellants' chose Zucker rats for treating because of their well-known possession of four distinct fat pads. Since the main component of the tissue mass was adipocytes, loss of 41%, 25% and 18% of the weight of the treated fat pads in Experiment E must have involved the disappearance of a large amount of fat. Appellants say that fat is metabolized. This is a credible assertion. If not metabolized, what happened to all that fat? Cf. claim 20: "...the body removing from said selected locations fat released from said adipose tissue"

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"Any practitioner in the art would be aware that in the disruption of any tissue, either enzymatically or physically, some of the cells located therein will be damaged and/or destroyed. This would have been particularly expected with adipose tissue because, as stated above, the adipocytes are actually nothing more than cellular storage bags of oil" (page 9, lines 3-7).

If this is intended to suggest that instead of being metabolized the 28% of the substance of the fat pads in Example E constituted damaged and/or destroyed cells and that they all went somewhere else in the body, there is no support for such an idea. That adipocytes are actually nothing more than cellular storage bags of oil does not mean that they are fragile. In both Lee et al. and Guidicelli et al., adipocytes survived shaking and centrifuging.

"Further, any practitioner in the art is aware of the basic facts retarding the body's metabolism.... It is only during a reduced calorie intake...that fat is released from adipose tissue and metabolized for energy."

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This acknowledges that metabolism of fat in the body is possible under some conditions, and does not deny that it could occur under other conditions.

Appellants in vivo method is patentable under § 103 over ~~the prior art~~ The two references for the reasons stated in Appellants Brief.

Respectfully submitted  
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